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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/868,469      | 09/24/2001  | Stephen J. Benkovic  | 6460-18-1           | 1582             |

7590 10/23/2006

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| EXAMINER |
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FRONDA, CHRISTIAN L

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/868,469

Applicant(s)

BENKOVIC ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,41-52 and 90-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11,14-40 and 53-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Claims 1-127 are pending in this application. Claims 12, 13, 41-52, and 90-127 have been previously withdrawn from consideration.
2. Claims 1-11, 14-40, and 53-89 are under consideration in this Office Action.
3. The rejection of claims 4-6 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite as being indefinite has been withdrawn in view of applicants' arguments and amendment to the claims filed 07/07/2006.
4. The rejection of claims 1-11 under 35 U.S.C. 102(b) as being anticipated by Holford et al. (Structure. 1998 Aug 15;6(8):951-6; PTO 1449 filed 6/15/2001) has been withdrawn in view of applicants' arguments and amendment to the claims filed 07/07/2006.
5. The rejection of claims 14-40 and 53-89 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Guan et al. (US Patent 5,643,758) in view of Holford et al. (Structure. 1998 Aug 15;6(8):951-6; PTO 1449 filed 6/15/2001) has been withdrawn in view of applicants' arguments and amendment to the claims filed 07/07/2006.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 1-11, 14-40, and 53-89 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments filed 07/07/2006 have been fully considered but are not persuasive.  
As stated in the previous Office Action, for claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient

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description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The claims as amended are still genus claim that are directed toward a genus of inteins; a genus of split inteins; a genus of split inteins derived from RecA, DnaB, PspPol-I, or Pfu inteins; a genus of split inteins derived from SspDnaE. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties. Furthermore, each genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses modified polynucleotides encoding modified Ssp DnaE N-intein and modified Ssp DnaE C-intein and their use in the preparation of modified enzymes including cyclic dihydrofolate reductase and cyclic pseudostellarin F. However, the specification fails to provide a written description of representative members of each claimed genus for which predictability of structure and function can be ascertained.

The disclosure of these polynucleotides is insufficient to be representative of the attributes and features of all species encompassed by the claims. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus.

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of a genus of inteins; a genus of split inteins; a genus of split inteins derived from RecA, DnaB, PspPol-I, or Pfu inteins; a genus of split inteins derived from SspDnaE.

Amending the claims to specifically recite modified polynucleotides encoding modified Ssp DnaE N-intein and modified Ssp DnaE C-intein and their use in the preparation of modified enzymes including cyclic dihydrofolate reductase and cyclic pseudostellarin F as disclosed in the specification may overcome the rejection.

### *Conclusion*

7. No claim is allowed.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**